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10/530,824	10/19/2005	Lynne Rainen	P-5729	7737

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EXAMINER	
UNDERDAHL, THANE E	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,824	RAINEN ET AL.	
	Examiner	Art Unit	
	THANE UNDERDAHL	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9,13-19,23 and 25-76* is/are pending in the application.

4a) Of the above claim(s) *28-76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9,13-19,23 and 25-27* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/2/09 has been entered.

This Office Action is in response to the Applicant's reply received 9/2/09. Claims 1, 3-9, 13-19, 23, 25-76 are pending. Claims 28-76 are withdrawn. Claims 2, 10-12, 20-22, and 24 are cancelled. Claim 1 has been amended. No Claims are new. Claims 1, 3-9, and 13-19, 23, 25-27 are considered in this Office Action.

Response to Applicant's Arguments— 35 U.S.C § 102/103

In the response submitted by the Applicant the following 35 U.S.C § 102 (b) rejections are withdrawn:

- remaining claims 1, 3-7, 10 and 11 based on Charlton in light of Wilhelm et al.

The following 35 U.S.C § 103 (a) rejections are withdrawn:

- remaining claims 1, 3-7, 13-19, 23, 25-27 over Charlton (1998, U.S. Patent 5,786,227) taken in view of Keana et al. (2001, U.S. Patent 6,184,210) and Wilhelm et al.
- remaining claims 1, 3-9, 13-19, 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton, Keana, and Wilhelm, and further in view of Degen et al.

The Applicant's amendments limiting that the device collects whole blood, is evacuated and requires both an anticoagulant and caspase inhibitor necessitated the above

withdrawal. The 35 U.S.C § 112 rejections are withdrawn as well because of the above amendments particularly that the "stabilization" is directed towards blood apoptosis.

New Rejections Necessitated by Amendment

Claim Objections

Claim 3 is objected to for not being further limiting of claim 1. The limitation in claim 3 that "the tube having a first end and a second end" is included in claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-9, and 13-19, 23-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 contains the phrase "an evacuated tube". While the Applicant has made progress in better defining this limitation the term "evacuated" is still unclear. The term is not explicitly defined in the Specification. Furthermore a broad use of the term "evacuated" has multiple meanings including "to remove the contents of:Empty" as supported by Merriam-Webster online. This definition would read on a tube that does not contain a sample or is empty. While the Applicant seems to indicate that paragraph [0017] of the Specification defines "evacuated" however this is not the case. M.P.E.P. §

2111.01 is clear that each limitation is to be provided the broadest reasonable interpretation. This includes other definitions commonly applied to terms. While the Applicant may be their own lexicographer (M.P.E.P. § 2111.01 IV) but paragraph [0017] does not clearly and precisely define "evacuated" as meaning only gasses since it does not exclude the other common definitions. The Applicant can remedy this rejection by simply amending the claims to indicate that the tube is evacuated to have a lower internal pressure that draws the blood into the chamber via a needle.

Also the limitation "whereupon collection, the whole blood is admixed with the stabilization agent and the anticoagulant" is unclear since this seems like a method step incorporated into this device claim. However the claim does not provide any structural limitation that could accomplish this step, therefore it is unclear how this "whereupon" clause is accomplished. Furthermore, the term "whereupon" is similar to a "wherein" clause, that does not provide any structure to the device to describe how this admixing limitaton is accomplished. M.P.E.P. § 2111.04 states that wherein type clauses are not further limiting since "Claim scope is not limited by ... claim language that does not limit a claim to a particular structure".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a

whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-9, 14-15, 17-19, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monro et al. (WO 98/06496) in view of Baust et al. (U.S. Patent # 6045990, 2000) and Xia et al. (Transfusion, 2000).

These claims are to a device for collecting whole blood comprising the following:

- an evacuated tube with a first and second end with a closure means for the first end and a reservoir portion for receiving the blood
- the reservoir portion has an anticoagulant
- the reservoir portion has a stabilizing agent a lyophilized caspase inhibitor in an amount effective to inhibit apoptosis upon collection

The device has a mechanical separating element disposed inside the tube. This element is partially coated with at least one stabilizing agent that is inert to the element. The separating member is a gel. Also the stabilizing agent can be separated from the element. The stabilizing agent can comprise a mix of caspase inhibitors. The apparatus alternatively comprises the following:

- carrier media or
- stabilizing media or
- at least one antioxidant or
- reducing agent or

o at least one buffering agent.

The limitation that the anticoagulant is spray-dried onto the interior wall is a product by process limitation. Product by Process claims are not limited by the manipulations of the recited steps, only the structure implied by the steps (M.P.E.P. § 2113). As such, these methods of preparation do no impart a functional relationship to the anticoagulant other than it is in contact with the interior wall of the device, and provides little patentable weight. The claims limit that the anticoagulant is EDTA.

Monro et al. teach a variety of containers for collecting whole blood (Monro, Figure 16 and pg. 21, lines 33-35). The Figure 16 container is actually 2 chambers; the primary chamber (#91) with a semi-permeable membrane (the separating element) that is inserted (disposed) inside a secondary chamber (#92) that is a reservoir for collecting blood. The membrane can be made from the inert gel polyalginate (pg 5, line 30). The container is evacuated to have a slight internal vacuum to draw the blood into the container, through the primary chamber to the secondary chamber (Monro, pg 22, lines 10-15). The container has a first end that is open but has a means to be closed via an air tight cap that can be inserted with a needle for sample collection (#95 and #951, Monro, pg 22, lines 10-20). The container has a second end as well. Monro et al. teach that "solutes, solvents or solutions may be placed in any chamber" (Monro, pg 22, lines 8 and 9). Monro et al. indicates these "solutes, solvents or solutions" could be anticoagulants (pg 22, line 10). One of ordinary skill in the art would think it obvious to put these "solutes, solvents or solutions" in contact with the semi-permeable membrane of the first chamber or physically separate from the semi-permeable membrane in the

second chamber since Monro et al. clearly teach that they can be placed in any chamber. Alternatively Monro et al. teach these solutes and solvents maybe coated onto the membrane (Monro et al. pg 8, lines 6-8). While Monro et al. does not specifically teach that these solutes are lyophilized, one of ordinary skill in the art would recognize that the solutes are dried in coated form and would predictably have similar properties to lyophilized solutes since the chemical properties would predictably be similar and thus obvious (M.P.E.P. § 2144.09).

What Monro et al. does not teach is that the container is a tube. However changes of shape are obvious absent evidence that a tube shape is critical (M.P.E.P. § 2144.04). Also Monro et al. does not teach that a caspase inhibitor is included in the container. However this is obvious in view of the teachings of Baust et al. They teach adding solutes such as the caspase inhibitor AI V (Baust, Fig 8, and lines 25-27). They teach that caspase inhibitor is to prevent apoptosis in cells that are stored (Bause, Abstract). They also teach that solutes such as anticoagulants such as EDTA, antioxidants such as vitamin E, pH buffers and radical scavengers (reducing agents) such as mannitol (Baust, col 5, Summary of Invention). Baust et al. also teach adding buffer media that carries these solutes (Baust, col 5, Summary of Invention). It would be obvious to apply these solutes to the invention of Monro et al. since they are for regulating apoptosis in cells. The motivation to regulate apoptosis in collected blood samples is provided by Xia et al. since they teach that blood platelets loose their viability in 5 to 7 days under standard storage conditions because of apoptosis caused in part by caspases (Xia, pg. 1320 col 2, pg 1322, col 2 and pg 1323 col 2). Therefore to ensure

the viability of collected blood samples it would be an obvious to one of ordinary skill in the art to improve the invention of Monro et al. by not only adding anti-coagulants but caspase inhibitors as well. This is a simple matter of applying the techniques of Baust et al. and Xia et al. to improve the device of Monro et al. to predictably reduce apoptosis of their blood samples which is obvious((KSR International v. Teleflex Inc. 550 U.S. ___, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007)). Therefore claims 1, 3-9, 14-15, 17-19, 25, and 26 are obvious in view of the above references.

Claims 1, 3-9, 13-15, 17-19, 23, 24, 25, and 26 rejected under 35 U.S.C. 103(a) as being unpatentable over Monro et al., Baust et al., and Xia et al. as applied to claims 1, 3-9, 14-15, 17-19, 25, and 26 above, and further in view Keana (U.S. Patent # 6184210, 2001).

The descriptions of claims 1, 3-9, 14-15, 17-19, 25, and 26 are recited in the 35 U.S.C § 103 rejection above and are applied here as well. Claims 13 and 23 limit that more than one caspase inhibitor is added to the device.

While Monro et al., Bause et al. and Xia et al. render obvious a blood collection container with a caspase inhibitor, they do not teach multiple caspase inhibitors. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Keana et al.

Keana teaches that compositions comprising several caspase inhibitors to regulate apoptosis (see Abstract). Keana teaches, like Monro et al. and Baust et al., that their compositions further comprise antioxidants (column 12, lines 45-50),

anticoagulants (EDTA; Example 23), buffering agents, or reducing agents (HEPES or glutathione; Example 23).

M.P.E.P. § 2144.06 states, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose .... [T]he idea of combining them flows logically from their having been individually taught in the prior art." It is therefore prima facie obvious to one of ordinary skill in the art to include multiple caspase inhibitors in the apparatus of Monro et al. and Baust et al. Therefore claims 1, 3-9, 13-15, 17-19, 23, 24, 25, and 26 are obvious in view of the above references.

Claims 1, 3-9, 13-19, 23, 25, 26 and 27 rejected under 35 U.S.C. 103(a) as being unpatentable over Monro et al., Baust et al., Xia et al. and Keana as applied to claims 1, 3-9, 13-15, 17-19, 24, 25, and 26 above, and further in view of Summaria et al. (U.S. Patent # 6139878, 2000).

The descriptions of claims 1, 3-9, 13-15, 17-19, 24, 25, and 26 are recited in the 35 U.S.C § 103 rejection above and are applied here as well. Claims 16 and 27 further limit that the device comprises trehalose and heparin. Which is not taught by Monro, Baust, Xia or Keana. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Summaria et al. (U.S. Patent # 6139878, 2000)

Summaria et al. teach that trehalose is a common additive for long term blood collection and storage (Summaria, col 5, lines 25-30). Also Summaria et al. teach that heparin along with other common anticoagulants such as EDTA and citrate are useful for blood collection and storage (Summaria, col 5, lines 15-20). M.P.E.P. § 2144.06 states "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."
Therefore it is prima facie obvious to one of ordinary skill in the art to add more trehalose and heparin to the device since these compounds are known to be useful for blood collection and storage. Therefore claims 1, 3-9, 13-19, 23, 25, 26 and 27 are obvious in view of the above references.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651